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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,432	11/23/1998	HOWARD A. FIELDS	03063-0231US	8029

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EXAMINER
BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/171,432	FIELDS ET AL.	
	Examiner	Art Unit	
	Brenda G. Brumback	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 March 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached.*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *70-72*.

   Claim(s) withdrawn from consideration: *1, 69, and 73-76*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER

DETAILED ACTION

Attachment to Advisory Action

Item #2:

Applicant's proposed claim amendments would raise new issues under 35 U.S.C. 112, 2nd paragraph, for the phrase "can include", as it is unclear whether the limitations following the phrase are part of the claimed invention (see MPEP § 2173.05(d)).

Additionally, applicant's proposed amendment to claim 72 would render the claim indefinite as the limitation "wherein the amino acid sequence from at least one of SEQ ID NOS:38-43 is excluded" appears to contradict the limitations of claim 70 (from which claim 72 depends), which recites an antigenically reactive HAV peptide comprising a portion of the P2A protein of HAV corresponding to AA 792-980. Applicant has identified AA 792-980 cited in the claims as corresponding to SEQ ID NOS:39-46 in Paper # 20 (filed 03/2//2002). Applicant's proposed claim amendment would thus appear to exclude the same sequences which are specifically recited in the base claim. Thus, if claim 72 were to be amended as proposed, it would contradict the base claim from which it depends and the claim would be indefinite.

Applicant's newly proposed claim 78 is indefinite because it is unclear if the claim is intended to exclude portions of all of SEQ ID NOS:38-43 or rather, if it is intended to exclude a portion of only a single member that is selected from those of the Markush group.

Applicant's newly proposed claim 79 appears to be drawn to an invention which is different in scope from the invention of original claims 70-72, as claim 79 recites an antigenically reactive HAV peptide comprising a portion of at least two HAV proteins and the original invention of claims 70-72 is drawn to an antigenically reactive HAV peptide comprising a portion of a single HAV protein. Applicant has elected a single species corresponding to a single protein, the P2A protein.

Applicant's proposed new claim 78 would be objected to for an informality in grammar, as the proposed claim appears to be lacking the article "a" between "of" and "sequence" in line 2.

Applicant's proposed claim 78 would also necessitate further search.

Applicant's proposed claim amendments would potentially raise the issue of new matter for the following proposed claim language:

"wherein the amino acid sequence from at least one of SEQ ID NOS:38-43 is excluded" (claim 72),

"wherein the peptide contains no portion of sequence selected from the group consisting of SEQ ID NOS:38-43" (claim 78),

"only a portion of at least two HAV proteins" (claim 79),

"wherein the sequence of the antigenically reactive peptide is not contained in any HAV polypeptide" , and

"wherein the antigenically reactive HAV polypeptide is not identical to a HAV polyprotein" (claim 81).

This matter might be resolved if applicant were to specifically point out where in the disclosure support for the newly recited material can be found.

Item # 5:

Upon entry of applicant's proposed amendment, the objection to the specification as not having an abstract submitted on a separate sheet would be withdrawn.

If entered, applicant's proposed amendment would overcome the portion of the rejection of claims 70-72 under 35 U.S.C. 112, 2nd paragraph, for "substantially similar"; however, the rejection would be maintained for "a portion" for the reasons of record. Applicant's arguments filed with the

present response regarding the "portion" language have been fully considered but they are not persuasive. Applicant's present claims encompass any and all antigenically reactive HAV peptides which comprise a portion of the P2A protein of HAV. A "portion" has been defined as "any fraction up to an including the complete item"; thus, the claimed portion encompasses as little as a single amino acid of the recited sequence. Consequently, applicant's claims encompass virtually all antigenically reactive HAV peptides because all such peptides would be expected to share at least one amino acid in common with the recited P2A protein. For this reason, the metes and bounds of applicant's claimed peptides cannot be determined and the claims are indefinite.

Upon entry of applicant's response, the portion of the rejection of claims 70-72 under 35 U.S.C. 112, 2nd paragraph, for "conservative variations" would be withdrawn, as applicant's arguments were persuasive.

Regarding the numbering system of the amino acids referenced in the claims, applicant's arguments have been fully considered but they are not persuasive because they fail to define any specific reference sequence upon which the claims are based. Absent such definition, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Regarding the outstanding rejection of claims 70-72 under 35 U.S.C. 103(a) as unpatentable over Chiron Corporation, applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant's argument that Chiron neither made nor tested any peptide corresponding to AA 792-848 has been previously addressed. Applicant's proposed claim amendments to eliminate the "substantially similar" language would not distinguish over Chiron because the proposed claims are drawn to an antigenically reactive HAV peptide comprising an amino acid sequence of a portion of the P2A protein. Therefore, for the reasons set forth *supra*, applicant's claims are not drawn exclusively to a

peptide corresponding to AA 792-848, but rather encompass virtually all antigenically reactive HAV peptides.

Applicant further argues that Chiron was wrong in teaching that peptides from the P2A protein would be antigenically reactive and cites Exhibits A-D "as providing evidence of the non-immunogenic nature of the non-structural proteins". This argument, however, is not understood, as each of the articles explicitly teaches that the nonstructural proteins are indeed antigenically reactive in immunoassays and also are immunogenic. Robertson teaches "Serial serum specimens from experimentally infected chimpanzees and humans naturally infected with hepatitis A verified the development of antibodies to P2 protein following infection" (see Exhibit B, the abstract). Robertson also teaches "P2 antibodies in naturally infected humans and experimentally infected chimpanzees appeared to develop during or after liver enzyme elevations" (see Exhibit C, page 78, first sentence of the second column). Jia teaches "All infected individuals tested had antibodies that recognized uncleaved P1 proteins as well as nonstructural proteins" (see Exhibit D, abstract). Thus, each of the referenced exhibits teaches the antigenic reactivity and immunogenicity of the P2 nonstructural protein.

Regarding applicant's argument that Chiron does not suggest any HAV peptide containing less than the complete portion corresponding to amino acids 792-848, applicant is referred to page 18 of the Chiron patent, claim 14, wherein Chiron claims an epitope derived from amino acids 792-848 of the HAV polypeptide sequence. Absent some evidence to the contrary, this would seem to explicitly suggest such a peptide.

Applicant's arguments regarding Chiron and fusion particle-forming proteins associated with HBV surface antigen are noted; however, Chiron specifically teaches individual peptides corresponding to portions of the P2A protein and specifically teaches making individual " ... polypeptides which may serve either as vaccines themselves, or as intermediates in the production of monoclonal antibody (Mab) preparations useful ... as diagnostic reagents" (see page 3, column 3, lines 2-48).

Applicant's argument that no peptide claimed by any new claim corresponds to the portion of the P2A protein disclosed in Chiron is not understood, as the newly added claims also recite the P2A protein of HAV corresponding to AA 792-980, as is recited in the originally presented claims. Chiron renders such a peptide obvious for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
Patent Examiner